

Compliance, satisfaction, and quality of life of patients with colorectal cancer receiving home chemotherapy or outpatient treatment: a randomised controlled trial

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Editorial by Kerr

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BMJ 2001;322:826-8

Abstract

Objective To compare chemotherapy given at home with outpatient treatment in terms of colorectal cancer patients' safety, compliance, use of health services, quality of life, and satisfaction with treatment.

Design Randomised controlled trial.

Setting Large teaching hospital.

Participants 87 patients receiving adjuvant or palliative chemotherapy for colorectal cancer.

Interventions Treatment with fluorouracil (with or without folinic acid or levamisole) at outpatient clinic or at home.

Main outcome measures Treatment toxicity; patients' compliance with treatment, quality of life, satisfaction with care, and use of health resources.

Results 42 patients were treated at outpatient clinic and 45 at home. The two groups were balanced in terms of age, sex, site of cancer, and disease stage. Treatment related toxicity was similar in the two groups (difference 7% (95% confidence interval -12% to 26%)), but there were more voluntary withdrawals from treatment in the outpatient group than in the home group (14% v 2%, difference 12% (1% to 24%)). There were no differences between groups in terms of quality of life scores during and after treatment. Levels of patient satisfaction were higher in the home treatment group, specifically with regard to information received and nursing care. There were no significant differences in use of health services.

Conclusions Home chemotherapy seemed an acceptable and safe alternative to hospital treatment for patients with colorectal cancer that may improve compliance and satisfaction with treatment.

Introduction

There is increasing interest in home care as an alternative to hospitalisation, particularly because of its potential for achieving cost savings by reducing levels of inpatient care.¹ However, evidence for cost savings from home care has been limited to specific pathologies such as chronic obstructive pulmonary disease.² The feasibility and cost effectiveness of home care depends on the setting studied, the type of treatment given, and the analytical methods used,³ and few trials have assessed the impact of home care on outcomes that would be relevant in the context of a given organisational change.

Most oncology centres give chemotherapy in an outpatient setting. However, chemotherapy is often cited as a procedure that may be suitable for home administration.^{4 5} The aim of the present study was to analyse safety, compliance, satisfaction with treatment, quality of life, and use of health services for adult cancer

patients receiving chemotherapy for colorectal cancer in an outpatient clinic compared with a home setting.

Participants and methods

Patients

Between October 1997 and October 1998 we selected patients referred to the medical oncology department of the Catalan Institute of Oncology with a diagnosis of colorectal cancer for whom treatment with adjuvant or palliative chemotherapy was indicated. To be eligible for our study, patients had to be between 18 and 75 years old, have a diagnosis of colorectal cancer, and be suitable for treatment with bolus fluorouracil based chemotherapy as adjuvant treatment or as treatment for disseminated disease according to the institutional protocol. The patients gave their written informed consent, and the hospital ethics and research committee approved the study protocol.

Randomisation

We randomly assigned the patients to receive chemotherapy either at the outpatient clinic (standard care) or at home, stratified according to the type of tumour (colon, rectum, or advanced disease). We calculated sample size to detect a difference of 8 (SD 3) between groups for self rated general health status.

Treatment

Adjuvant chemotherapy consisted of bolus fluorouracil with levamisole for five consecutive days during the first cycle and once a week thereafter until completion of 12 months' treatment, or bolus fluorouracil with folinic acid for five days a week (or three days in the case of combined chemoradiotherapy) every four weeks until completion of six cycles of treatment. Palliative chemotherapy consisted of bolus fluorouracil with folinic acid for five days a week every four weeks until completion of six to eight cycles if disease was stable or until disease progression was observed. Patients in the home chemotherapy group were required to visit the hospital every four weeks. A trained nurse delivered the home chemotherapy.

Outcome measures

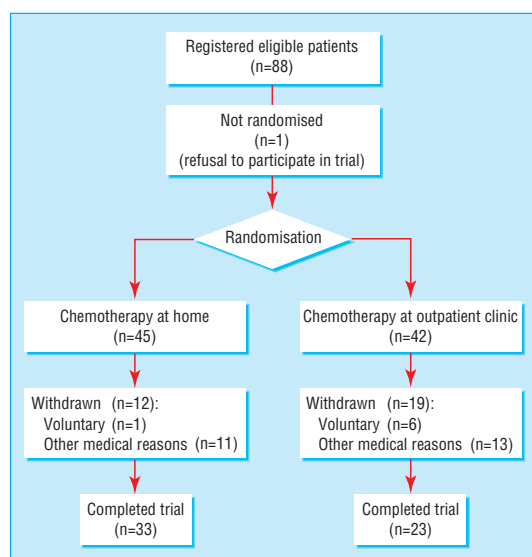
Treatment toxicity—We measured and recorded treatment toxicity every four weeks using the ECOG classification.⁶

Withdrawal from trial—We classified reasons for withdrawing from the trial as unacceptable toxicity of chemotherapy, disease progression, or voluntary withdrawal not related to previous causes. Only the last category was considered as patient non-compliance.

Use of healthcare resources—We asked patients about any unplanned use of primary care or emergency department or hospitalisation or any other use of health services not covered in the protocol.



The full version of this paper is available on the BMJ's website



Progress of participants through trial

Quality of life—We measured patients' quality of life with the EORTC QOL-C30 questionnaire.⁷ This includes five functional scales (physical, role, emotional, cognitive, and social), a global health status quality of life scale, and single measures of symptom severity (fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties).

Satisfaction with health care—We assessed patients' satisfaction using a questionnaire translated into Spanish for this study.⁸ This included several items that measured general satisfaction with health care received, availability of doctors, nursing availability (related to waiting time), continuity of care, personal qualities of nurses (related to perceived interest in the patient), and communication with doctors and nurses.

Statistical analysis

We calculated point estimates and 95% confidence intervals for the differences between groups in percentages, means, and change between the initial and final questionnaire scores. We used analysis of variance for repeated measures to compare patients' quality of life and satisfaction scores, both before and after treatment and between the groups.

Results

We recruited 87 patients to the trial (figure). The groups were comparable at baseline (table 1).

Withdrawals and treatment toxicity—Voluntary withdrawals from chemotherapy were significantly higher in the outpatient treatment group (difference 12% (95% confidence interval 1% to 24%)). Overall, one in three patients did not complete chemotherapy (table 2).

Use of healthcare resources—The groups showed no significant differences in use of healthcare resource for unplanned visits.

Quality of life—There were no differences between groups in quality of life, neither at the initial assessment or once treatment was completed nor in terms of changes in scores during the trial. Insomnia was the symptom with the highest impact on the quality of life (final score of 32 in outpatient treatment

group *v* 23 in home treatment group), followed by fatigue (30 *v* 29), and pain (19 *v* 20). For more detail, see the full version of this paper on bmj.com.

Satisfaction with health care—There were no differences between groups in scores on the initial satisfaction questionnaire. However, when we assessed patients' satisfaction after completion of treatment we found a significant difference between groups in the perception of nursing availability, with the hospital outpatients considering that they had to wait longer to receive chemotherapy than the patients treated at home (table 3). Communication with nurses and the personal qualities of the nurses were also rated more highly by the home group. Global satisfaction with health care was higher in the home group, but the difference was not significant.

Discussion

The results of this study indicate that home chemotherapy for patients with colorectal cancer is a safe and acceptable alternative to outpatient hospital treatment. No major complications occurred, showing that this type of chemotherapy can be safely administered outside hospital. From the point of view of implementation and impact on healthcare systems, it is worth noting that we found no differences between groups in use of non-programmed health resources, suggesting that home chemotherapy did not increase the use of other health services such as primary care or emergency departments.

Study limitations

Our study was limited to a specific treatment for colorectal cancer. This treatment was common at the time our study was planned, but the results may not apply to newer or more complicated chemotherapy regimens. However, our results would probably be applicable to other tumours and some chemotherapy programmes.

We did not perform a detailed cost analysis because the study was planned under a hospital perspective in a context of increasing demand for cancer treatments, where it was fairly obvious that a home programme would require additional resources. However, home

Table 1 Baseline characteristics of 87 patients with colorectal cancer assigned to chemotherapy at hospital outpatient clinic or at home. Values are numbers (percentages) unless stated otherwise

| Characteristic | Treatment | |
|-----------------------------------|-------------------|-------------|
| | Outpatient (n=42) | Home (n=45) |
| Male | 24 (57) | 21 (47) |
| Mean age (years) | 60.8 | 59.8 |
| Site of tumour: | | |
| Colon | 19 (45) | 21 (47) |
| Rectum | 14 (33) | 13 (29) |
| Advanced disease | 9 (21) | 11 (24) |
| Unacceptable treatment toxicity*: | | |
| Haematological | 13 (31) | 12 (27) |
| Biochemical | 0 | 0 |
| Clinical | 15 (36) | 12 (27) |
| Treatment type: | | |
| Palliative | 8 (19) | 9 (20) |
| Adjuvant | 34 (81) | 36 (80) |
| Preoperative radiotherapy | 3 (7) | 2 (4) |
| Postoperative radiotherapy | 12 (29) | 14 (31) |

*Grade 3 or 4 on ECOG classification.

Table 2 Compliance with treatment by 87 patients with colorectal cancer assigned to chemotherapy at hospital outpatient clinic or at home. Values are numbers (percentages) unless stated otherwise

| Reason for non-compliance | Treatment | | Difference in % (95% CI) |
|-------------------------------------|-------------------|-------------|-----------------------------|
| | Outpatient (n=42) | Home (n=45) | |
| Voluntary withdrawal from treatment | 6 (14) | 1 (2) | 12 (0.6 to 24) |
| Withdrawal for other reasons* | 13 (31) | 11 (24) | 7 (-12 to 25) |
| Total | 19 (45) | 12 (27) | 18 (-1 to 38) |

*Unacceptable toxicity (16 cases), disease progression (6), doctor's discretion (2).

Table 3 Satisfaction* with medical care reported by 56 patients with colorectal cancer after chemotherapy at hospital outpatient clinic or at home. Values are means (SD) unless stated otherwise

| Type of care | Treatment | | Difference in means (95% CI) |
|-------------------------------|-------------------|-------------|---------------------------------|
| | Outpatient (n=23) | Home (n=33) | |
| Health care in general | 78 (19) | 86 (13) | -8 (-17 to 0) |
| Availability of doctor | 13 (17) | 13 (19) | 0 (-10 to 10) |
| Availability of nurse | 54 (16) | 87 (7) | -33 (-39 to -26) |
| Continuity of care | 51 (21) | 54 (23) | -3 (-16 to 9) |
| Personal qualities of nursing | 84 (15) | 98 (6) | -14 (-20 to -8) |
| Communication with nurse | 82 (25) | 100 (0) | -18 (-26 to -9) |
| Communication with doctor | 70 (26) | 70 (22) | 1 (-12 to 14) |

*Satisfaction scales range from 1 to 100, with higher scores representing greater satisfaction.

What is already known on this topic

Home chemotherapy programmes have been proposed as an alternative to hospital treatment

However, they are more costly, and there is little evidence on their impact on outcomes such as compliance, quality of life, or use of other health services

What this study adds

Home chemotherapy was not associated with an increased use of health services such as primary care or emergency departments

Home chemotherapy had no effect on patients' quality of life but increased their compliance with treatment and satisfaction, particularly with regard to nursing care

Home chemotherapy seems an acceptable and safe alternative to outpatient treatment that may improve compliance with treatment

chemotherapy could be an economically realistic alternative to hospital treatment if we consider indirect benefits to patients.⁹

Conclusions

This study is one of the first trials in chemotherapy to evaluate the impact of organisational change on a variety of outcomes. It is surprising that, while considerable effort is devoted to assessing the benefits and risks of drugs, much less attention is paid to understanding how the mode of administration affects important outcomes such as use of health services or satisfaction with care. A recent review of the effect of home care programmes on the quality of life of patients with incurable cancer and on use of hospital resources concluded that the effectiveness of such programmes remains unclear and that research is needed before

such programmes are expanded.¹⁰ Our study contributes to the assessment of home care for cancer patients and has shown that home chemotherapy could be advantageous for patients by increasing satisfaction and compliance with treatment.

We thank the EORTC for permission given to use the EORTC QOL-C30 quality of life questionnaire. We thank C Fernandez, M Garcia, X Puig, and V Moreno for helping to make this study possible, and M Herdman for his revision of the English version of this manuscript. Preliminary results of this study were presented at the seventh meeting of the Spanish Society of Medical Oncology and at the sixth annual meeting of the International Society for Quality of Life Research.

Contributors: JMB and JRG had the idea for the study, obtained the grant, and managed the project. EM and AS-H supervised the study and contributed to the study design and data collection. EM was the monitor of the trial. JAE conducted the analysis and helped in interpreting the data. MN, JLLP, and MM supervised the medical, pharmaceutical, and nursing processes and helped in interpreting the data. JMB and AS-H wrote the first version of the paper, all authors reviewed the paper and contributed to the final version. JMB and JRG are guarantors for the study.

Funding: Research grant from the Catalan Agency for Technology Assessment in Health Care (contract 1996/273).

Competing interests: None declared.

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(Accepted 5 January 2001)

Endpiece Wise advice

"If I'd known I was gonna live this long, I'd have taken better care of myself."

Eubie Blake (1883-1983)
in the *Observer*, 13 February 1983

James Hubert Blake was born on 7 February 1883 in Baltimore, Maryland, to John Sumner Blake, a stevedore, and Emily Johnston Blake, a laundress. Both his parents had been slaves. Eubie, jazz pianist, song writer and composer, is best remembered for "I'm Just Wild About Harry," President Harry Truman's campaign song, and the still popular "Memories of You." Eubie pioneered the first black show on Broadway, New York, in 1921. He played at the White House in 1978 for President Jimmy Carter to mark the 25th anniversary of the Newport Jazz Festival.

Submitted by Fred Charatan,
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